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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,392	08/13/2001	Theodore E. Spielberg	15343-0028C3	6911

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CESARI AND MCKENNA, LLP  
88 BLACK FALCON AVENUE  
BOSTON, MA 02210

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/12/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/928,392

Applicant(s)

SPIELBERG, THEODORE E.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

The Election filed January 15, 2003 (Paper No. 3) in response to the Office Action of December 16, 2002 is acknowledged and has been entered.

Claims 1-16 are pending in the application.

Claims 9-10 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-8, and 11-16 are currently under prosecution

Applicant's election with traverse of Group I, claims 1-8 in Paper No 3 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and III are directed to the same statutory invention. This argument has been considered and is found persuasive. Thus, Groups I and III have been joined. Applicant's further argue that the claims in Group II are also directed to the invention as claimed in Groups I and III. Applicants argue that it should be apparent that the flattened macrochamber taught by the claims in Group II is directed to the same statutory invention as the endocrine cell microdisks taught by the claims in Groups I and III. This argument has been considered but is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in Paper No. 2. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group.

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For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

### *Specification*

The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application is a continuation of US application No. 09/397,780, filed September 16, 1999, now abandoned.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a) because they fail to adequately represent the depiction of concavities or the inclusion of tabs as described in the specification on page 9. For example, the specification teaches page 9, line 15+ that concave depressions are formed by fusing certain surfaces. In regards to the inclusion of tabs, the specification further teaches (page 8, line 20) that those portions of the disk faces in the vicinity of the tab will assume a concave geometry relative to more remote portions of the opposed faces which will assume a generally convex geometry as the disk is filled. These tabs or columns may be provided at a number of locations within the disk so as to form a number of concavities.

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction

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or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6, 8, and 14 recite the limitation said "disk". There is insufficient antecedent basis for this limitation from which these claims depend.

Claims 15-16 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15 and 16 recite "at least one tab" or "a plurality of tabs". The recitation of such "tabs" is vague and indefinite because the disclosure does not adequately define nor teach what is included or excluded as a tab, its composition, or where to obtain such a tab. The specification only teaches (page 8) that a thin, flat tab or a thin column may be employed as an interior structural element. What exactly is a "tab"? As written, the metes and bound of the claims cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang *et al.* (Biomaterials, January 1994, Vol. 15(2): 113-120.)

Yang *et al.* teach an endocrine cell microdisk comprising a discoid microporous encapsulated endocrine cell for transplantation into an animal body to correct a hormonal deficiency wherein the endocrine cell is an insulin producing cell (islets). Yang *et al.* further teach that the disc is 2mm thick and 15 mm in diameter (page 114, 2<sup>nd</sup> column and Figure 1, page 115) which reads on a disc having a ratio of diameter to thickness of at least 4 or in the range of from 6 to 20. Yang *et al.* further teach that the discs are maintained by an internal joining structure, agarose hydrogel. The microdisk of Yang *et al.* further encompasses a microporous membrane having first and second opposed faces joined together at the periphery thereof and forming an extended flattened structure of lateral extent substantially greater than the maximum thickness between the surfaces wherein said lateral extent is at least four times said thickness.

Although Yang *et al.* do not specifically discuss the geometry of the disc, (i.e. the ability to form concave faces), the specification does not specifically define the limitations of such shapes. The specification only generally teaches (page 8) how the concave shapes may be formed. For example, if the interior cavity of the disks are not completely filled with cellular and related material, one or more of the opposed faces, when formed of sufficiently thin and pliable material, *will conform itself* generally to the surface of its liquid contents, assuming at least a “saucer” shape. On the other hand, if the faces of the disk are of sufficient thickness and strength,

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the disk may be molded with the concavity formed in place. Thus, inherently, the discs of Yang *et al.* have at least one concave face or two opposed concave faces maintained by internal joining structure and can generally form the shape of an erythrocyte.

The following prior art is provided and made of record (although not relied upon) is considered pertinent to applicant's disclosure:

Antanavich *et al.* (US Patent No. 5,855,613)

Antanavich *et al.* (US Patent No. 6,165,225)

Soon-Shiong *et al.* (US Patent No. 5,879,709)

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

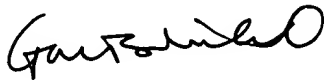
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Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
March 11, 2003

A handwritten signature in black ink, appearing to read "Gary B. Nickol", followed by a large, stylized capital "O".